REMARKS

Claims 29-33 and 35-74 are in the application.

FORMAL REJECTIONS

Claim 51 is rejected as being allegedly indefinite. Applicants have amended claim 51 to now change both occurrences of "model" within the original claim to "tolerance", thus providing proper antecedent basis.

Claims 51, 60 and 67-73 are rejected as failing to comply with the enablement requirement of 35 U.S.C. § 112, and for including alleged new matter.

Claim 51 has been corrected to change "risk model" to "risk tolerance". In the prior amendment, only the first occurrence was changed. It is respectfully submitted that this change comprises neither a new issue nor new matter, as it was clearly a technical error, with the intent of applicant made clear. Entry of this amendment will place the application in better form for appeal and resolve the issue raised by the Examiner.

Applicant believes that the Examiner is in error for determining that the claimed subject matter is not a part of the original disclosure, and therefore prematurely terminated the Examination. Since the Examiner indicated that claims 51, 60 and 67-73 were not "further examined on the merits", to which applicant is entitled according to patent office rules and regulations, and as provided by the Manual of Patent Practice and Procedure, if it is found that these claims are supported by the disclosure, the finality of the rejection must be withdrawn, and prosecution on the merits reopened, if required.

Per the Examiner note 3 in MPEP 706.03o (Emphasis added):

> 3. If new matter is added to the claims, or affects the claims, a rejection under 35 U.S.C. 112, first paragraph, using form paragraph 7.31.01 should also be made. If new

matter is added only to a claim, an objection using this paragraph should not be made, but the claim should be rejected using form paragraph 7.31.01. As to any other appropriate prior art or 35 U.S.C. 112 rejection, the new matter must be considered as part of the claimed subject matter and **cannot be ignored**.

Claim 60 is rejected because the original disclosure allegedly "does not state that the 'likelihood of adoption' is part of the optimization process, or is a variable in the optimization process." Specification states:

> The present invention provides an **optimization** of nutritional supplementation **based on models that allow prediction** of a change in health from an existing status, as a result of administration of a plurality of nutritional supplements. Relevant to various embodiments of the invention are activity of each nutritional supplement, desired change in status, toxicity and adverse effects of nutritional supplements, interactions between nutritional supplements and other factors, **cost and economics** of the nutritional supplementation, and risk, both positive and negative. (Page 3, lines 2-7).
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> **A preferred embodiment of the invention employs an economic optimization** of nutritional supplementation. Therefore, in addition to determining which nutritional supplements are appropriate, the cost of each component or the proposed nutritional supplementation as a whole is determined and **used to achieve the maximum health benefit for given economic factors, such as a budget.** Therefore, as a further aspect of this embodiment, the cost structure of combination supplements and quantity discounts are considered. In addition, third party health insurers or life insurers may provide payments, discounts or rebates for the proposed regimen. Where an economic model is not explicitly employed, a user may be presented with one or more proposals having differing nutritional supplement costs, which may then be selected by the user. (Page 4, line 17-Page 5, line 2).
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> The present system provides an individually tailored proposal for nutritional supplementation or modification of intake. Being a proposal, and given the nature of mandates of dietary intake, the proposal may be accepted or rejected by the individual. Therefore, another embodiment of the invention involves an interactive process for arriving at a proposal, as well as a correction of optimization based on a deviation from a proposal. **In this case, the cost optimization and risk analysis potentially play an important roles in a statistical analysis to arrive at a proposal.** Since it would be expected that, except in the case of total parenteral nutrition, no absolute dietary schedule will be maintained, and further that it is primarily those individuals whose diets are most aberrant initially who are recalcitrant to change, the optimization proposal must include leeway for deviations. (Page 7, lines 4-13).
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> **A preferred embodiment includes an economic optimization** because, without this factor playing an explicit role, the "more is better" theory may produce a proposal

which is untenable. Known systems which attempt to optimize nutrition perform economic optimization in one of two ways. First, the public health model selects cost levels designed to do the most good for the most people. Some persons will receive a suboptimal dose, while others will receive little incremental benefit or even suffer toxic effects. Further, some persons will be asked to spend more than a reasonable amount, while others will have excess disposable funds without guidance as to how these funds should best be employed. Thus, the public health model does not account for an individual and his own specific factors, including budget. **Second, an incomplete or limited economic analysis may be performed without the benefit of a linked health model.** For example, an individual who visits a health food store and selects supplements performs a limited economic model, e.g., "that costs too much", in the selection of items for purchase. **By linking the economic model with an individual health model, the benefits of a personalized proposal at acceptable cost is obtained.** Further, by allowing a statistical error in the actual diet as compared to the proposed diet, the optimization may produce a better "real-world" result. (Page 8, lines 9-23).

In theory, an economic based model may result in a highly skewed proposal, with high doses of relatively cheap components and without any expensive components. However, often, temperance and variety are desired, and thus amounts of some nutritional supplements are limited and others added, even though these result in reduced benefits according to a strict scientific analysis. Thus, a perceived benefit of a nutritional supplement may be in excess of a rational analysis of the potential benefit based on a review of existing scientific data. **Thus, a health model may include an analysis of a perceived benefit of a component, rather than necessarily a scientific analysis.** Further, it is noted that, in accordance with the scientific method of analysis of nutritional supplementation, studies may fail to show a benefit, or produce contradictory findings, even for nutritional supplements of real value. For example, ginseng is believed by many to be beneficial, but many scientific studies have failed to reveal a health benefit. This does not mean, however, that the proposed benefit of a component is not real. Another limitation of scientific methods is that they emphasize dose-response relationships over balance. However, a perception of an individual may be that supplementation of smaller amounts of many different components is preferable to megadoses of a small number of nutritional supplements. Another limitation of typical scientific studies is a difficulty in proving subtle long-term effects of small doses. (Page 10, lines 1-17).

The system thus seeks to determine, based on a set of personal preferences and constraints, as well as a health model and optionally a personal economic optimization model, an optimal proposal for nutritional supplementation. Public health concerns partially defer to individual health considerations. Further, absolute health mandates defer, within limits, to personal preferences and optionally cost tolerance. (Page 12, lines 13-17).

Based on an estimation of the present status of the consumer, the system then seeks to propose specific changes and nutritional supplements, **in accordance with the health theory, expressed preferences, and optionally within the constraints of the economic model, to maximize the expected benefit to the consumer.** The consumer

then interacts with the system to "tune" the proposal based on personal preferences. After acceptance, the consumer may then execute the proposal by purchasing the recommended supplements. As stated above, the purchase system may be linked to the terminal, in communication with the terminal, or completely separate. (Page 13, lines 13-20).

If a consumer alters his preference, or the health theory is altered, either by selection of a new theory by the consumer or an alteration in the theory based on new evidence, **the subsequently generated proposals may also be altered**. However, the system will continue to rely on closed loop feedback to personalize the proposals. (Page 14, lines 9-12).

The present system may also include a further related concept, **a model for optimization of health, which differs from the health model by allowing statistical analysis of risks and benefits, as well as contingent benefits**. (Page 16, lines 1-3).

In practice, these models are preferably provided as modular objects in a computer system, allowing one object to be substituted, altered or updated without simultaneously requiring consideration of corresponding or compensatory changes in other models which are not dependent on the changed object. Of course, the resulting optimization is a dependent object and must be recomputed after a change in a parent object. Each model therefore includes a set of formulae or parameters, which may be evaluated in context. **The evaluation is a statistical or multifactorial optimization to determine a best proposal.** As stated above, based on external inputs, factors of the model may be constrained. Further, closed loop feedback may be used to update or personalize the model for more accurate determinations. (Page 16, line 22-page 17, line 7).

The proposal need not be limited to nutritional supplements, and therefore changes in diet, activity or exercise may also be included in the proposals. It is noted that great changes in diet, activity and exercise are difficult to effect, and therefore such proposals may be of limited benefit. **In fact, since non-compliance rates are expected to be high, an optimization based on a proposal requiring distinct efforts is likely to be rejected or ignored. On the other hand, simple changes in diet, which are likely to be adopted, may be very efficacious.** Thus, on a pragmatic basis, the proposal preferably emphasizes small dietary changes and a regimen of pills and/or supplements, even where an equivalent change might be possible through extensive dietary modification or restriction. The user may therefore weight a relative expected importance of normal diet as compared to nutritional supplements. (Page 19, lines 10-19).

This distinction is also drawn elsewhere in the optional optimization process. The health optimization model factors in risk tolerance as a separate factor. Thus, a consumer with high risk tolerance might give greater emphasis to alternative medicine concepts than a lower risk tolerance consumer. This risk tolerance may be explicit, i.e., a person who expressly desires a higher risk (and higher potential reward) proposal, or implicit,

i.e., a person who is healthy and can tolerate adverse effects better than an ill or fragile person.

On one hand, a Japanese user would likely find comfort in a traditional Japanese health model, which in western medicine is considered "alternate". **On the other hand, an orthodox American medical practitioner using the nutritional supplement optimization system is unlikely to adopt substantial contributions from alternative medicine sources.** (Page 21, line 22-page 23, line 8).

The interface to the system is preferably an interactive graphic user interface, allowing the consumer to make incremental selections and make modifications to selections during a session. The use of screen buttons, hot links, menus, dialogue boxes and other typical graphic user interface elements is therefore preferred. **Through use of the system, the preferences of the user may be determined, and present further data and selections based on the determined preferences.** Such a learning interface may allow efficient interaction between the machine and user. The system may be, for example, a Pentium® personal computer, Apple Power PC®, UNIX system, or other known type of computer system. The operating system is, for example, Windows for Workgroups 3.11, Windows 95, Windows NT, Macintosh Operating System, SunOS, Netscape/Java, or other known type. (Page 22 line 22-page 23, line 8).

Finally, a health optimization model 28 is selected which modifies the health model output based on the concept of **risk and benefit**. Thus, a user indicates explicitly a subjective risk tolerance, while implicit determinations of objective acceptable risk are also determined. **This model is statistical in nature**, and seeks to alter the aggressiveness of the proposal based on the models. It is noted that the aggressiveness weighting relies on the underlying health model. If a user seeks moderate aggressiveness in nutritional supplementation, but not necessarily high risk, then a different health model is preferably adopted which proposes the desired regimen. Generally, it would be strongly suggested to users to avoid high risk or very aggressive models except under professional supervision.

In generating the proposed nutritional supplementation 29, it is noted that the various models may have global minima or maxima and local minima or maxima, and therefore known searching algorithms may be employed to select a preferred "operating point", i.e., to optimize the proposal. **Further, it is also noted that full compliance is rarely obtained, so that the models or the health optimization model may precompensate for an expected degree of non-compliance. This expected degree of non-compliance may be estimated or based on subjective data or retrospective compliance data.** (Page 28, lines 3-18).

In particular, it is believed that the passages at Page 8, lines 9-23; Page 12, lines 13-17; Page 13, lines 13-20; Page 14, lines 9-12; Page 19, lines 10-19; Page 21, line 22-page 23, line 8; Page 22 line 22-page 23, line 8; and Page 28, lines 3-18 are most pertinent to this issue. It is

respectfully submitted that one of ordinary skill in the art would interpret the specification to clearly and unambiguously teach a system which "emphasizes a likelihood of adoption of the proposal by a user" (claim 60) or "automatically optimizing an economically efficient presentation of selections dependent on a joint analysis of the associated economic parameter and risk with respect to a likelihood of user adoption of a selection" (claim 67).

The specification includes an express discussion of the adverse results of making a proposal which is not likely to be adopted, the desirability of generating a proposal which is likely to be adopted, and providing feedback in accordance with the preferences of the user to assure that the proposal meets the users preferences for adoption. Therefore, applicant requests reconsideration of this rejection.

ART REJECTION

Claims 29-33, 35-50, 52-59, 61-66 and 74 are rejected under 35 U.S.C. § 102(e) as being anticipated by Mayaud, US 5,845,255.

The Examiner asserts that the allergies discussed by Mayaud are statistical risks. In fact, it is believed that the Examiner misreads Mayaud. Mayaud does not include allergies are a component of the drug profile, but rather as a component of the patient profile. Indeed, even were the likelihood of an allergic response part of a drug profile, there is no teaching or suggestion how that information might be used--for example if there is a 1% chance that a randomly selected patient might be allergic to a penicillin, there is simply no teaching how this information might be presented to a user or employed by a user. A simple alert would be relatively meaningless, and no more complex analysis is available. Thus, even were this information available, it is not used in accordance with the presently claimed invention.

A statistical risk is one which may or may not exist, and is subject to acknowledged false-positive and false-negative errors. Further, when treated as a statistical risk per se, the probabilities inherent therein must be respected in the analysis. That is, as part of a patient medical record, an allergy is treated as an absolute risk, and competent medical professionals would not, without further investigation, consider that the record might be false and therefore may be ignored. The Examiner, in assigning the allergy information discussed in Mayaud to correspond to the statistical risk, eliminates the fundamental meaning of an express claim term (statistical), which is an impermissible claim interpretation.

According to Mayaud, a drug for which an allergy alert is triggered remains listed, and apparently the presentation is unaltered, except for that alert. Likewise, an "unnecessarily expensive drug" is also denominated by a simple warning. Clearly this separate consideration of cost and risk does not anticipate a joint optimization thereof, and leads to a materially different result. That is, Mayaud does not alter the presentation (e.g., ranking) of responses due to statistical risk, while a joint optimization would, for example, yield this result.

The final element of claim 29 requires: "presenting the subset of records automatically jointly optimized based on the determined economic parameters, and the statistical risk associated with the selected record." There is simply no teaching or suggestion in Mayaud to conclude that the presentation of records is jointly optimized based on both economics and statistical risks. In the cited passage, the risk of allergic reaction (or other enumerated "risks") are provided as an alert separate and apart from the presentation of records. That is, even if a drug is contraindicated, and therefore non-optimal, it is still presented. Therefore, it is quite clear that there is simply no joint optimization, as required by claim 29.

Likewise, claim 44 requires: "presenting the set of records automatically optimized based on both the determined economic parameters and the determined statistical risk," and claim 59 requires: "automatically jointly optimizing a presentation of the records based on both the economic parameters and the determined statistical risk." Mayaud does not teach or suggest any automatic optimization based on both economic factors and determined statistical risk, and indeed, it is not clear that Mayaud in any way determines any statistical risk.

Claim 67 requires: "automatically optimizing an economically efficient presentation of selections dependent on a joint analysis of the associated economic parameter and risk with respect to a likelihood of user adoption of a selection." This claim therefore involves a further aspect to the optimization, that it be with respect to a likelihood of user adoption.

Response to Examiner's Analysis

Applicant has presented herein-above support for the contention that the optimization is based on a likelihood of adoption. While it is true that the individual passages on page 19 do not discuss the optimization as a whole, they clearly express motivation and guidance for the optimization detailed elsewhere. In context, it is clear that the optimization is dependent on a likelihood of adoption--if not, why do we care about the user's preferences and feedback?

While it is true that Mayaud does discuss analysis of drug cost, this appears to be independent of other analyses. Therefore, the optimization is not "joint". The system does not suggest drugs based on cost, and particularly disavows this scheme (see Col. 39, line 52-54): "...improving formulary compliance and reducing overall drug costs, **without restricting a physician's choices**."

Applicant discusses above the "statistical risk" issue.

It is therefore believed that the rejections are overcome, and the application is allowable.

Respectfully submitted.

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